

Presumably, other inhibitors of telomerase are known and/or will be discovered in the future. But all of this has nothing to do with applicants' discovery, embodied in claim 1, that these compounds can be used to reduce hair growth.

The approach taken in claiming the present discovery is very similar to the approach taken by applicants to claim discoveries related to reducing hair growth, by inhibiting other enzymes, in many other United States patents. See, for example, most of the United States patents listed on page 5, lines 6-9, of the specification. See also most of the references AA-AS listed on the Form 1449 that has been reviewed by the Examiner.

35 U.S.C. § 112, ¶ 1 Rejection

Applicants will focus on claim 1 in this analysis. Claims 33-48 are enabled for at least the same reasons. Applicant will first explain why claim 1 satisfies the requirements of 35 U.S.C. § 112, ¶ 1, and then will try to address the specific concerns of the Examiner.

As explained by the Board of Appeals in Ex parte Forman, 230 U.S.P.Q. 546, 547 (1986), 35 U.S.C. § 112, ¶ 1 requires applicants to provide a sufficient disclosure

To enable one having ordinary skill in the relevant field to practice the invention claimed therein without the exercise of undue experimentation.

The Board went on to explain the factors that are considered in deciding when experimentation becomes "undue" (id.):

The determination of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness, having due regard for the nature of the invention and the state of the art: Ansul Co. v. Uniroyal, Inc. 169 U.S.P.Q. 759, 762 (2d Cir. 1971).

* * *

The factors to be considered have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the predictability or unpredictability of the art and the breadth of the claims. In re Rainer, 52 CCPA 1593, 347 F.2d 574, 146 USPQ 218 (1965); In re Colianni, *supra*.

A person skilled in the art, reading applicants' specification, would be able to practice the claimed invention -- reducing hair growth by topical application of an inhibitor of telomerase -- without undue experimentation. Therefore, applicants have met the requirements of 35 U.S.C. § 112, ¶ 1.

Applicants will apply each of the factors mentioned in Forman to the current facts, and explain why the facts demonstrate that the claimed invention can be practiced without undue experimentation. Applicants will begin with a key factor mentioned in Forman, the nature of the invention.

Nature of the invention

What is meant by "the nature of the invention" was discussed in the Ansul decision cited by the Board in Forman. In Ansul the court explained that inventors who discover "a new use for existing composition" are entitled to broad, generic claims even if the inventors have not disclosed every potential embodiment of the invention (see 169 U.S.P.Q. at 762).

What this means in the context of the present invention is that applicants are not required to disclose every conceivable inhibitor of telomerase in order to be entitled to a generic claim. As explained previously, the invention is not inhibitors of telomerase. Rather, like in Ansul, applicants discovered a new use (reducing hair growth) for compounds (telomerase inhibitors) that are well known. The court addressed this very issue in In re Fuetterer, 138 U.S.P.Q. 217, 223 (1963):

Appellant's invention is the combination claimed and not the discovery that certain inorganic salts have colloid suspending properties. . . . The invention description clearly indicates that any inorganic salt which has such properties is usable in his combination. If others in the future discover what inorganic salts additional to those enumerated do have such properties, it is clear appellant will have no control over them per se, and equally clear his claims should not be so restricted that they can be avoided merely by using some inorganic salt not named by appellant in his disclosure. The only "undue burden" which is apparent to us in the instant case is that which the Patent Office has attempted to place on the appellant.

Amending claim 1 to cover only the use of inhibitors that applicants have named would allow competitors after reviewing the resulting patent to use other inhibitors of telomerase to reduce hair growth in order to avoid literally falling within the claim while still taking advantage of applicants' contribution. This result would be unfair to applicants. The Court of Customs and Patent Appeals, in In re Goffe, 191 U.S.P.Q. 429, 431 (1976), explained why:

For all practical purposes the board would limit appellant to claims involving the specific materials disclosed in the examples, so that a competitor seeking to avoid infringing the claims would merely have to follow the disclosure in the subsequently-issued patent to find a substitute. However, to provide effective

incentive, claims must adequately protect inventors. To demand that the first to disclose shall limit his claims to what he has found will work or to materials which meet the guidelines specified for "preferred" materials in a process such as the one herein involved would not serve the constitutional purpose of promoting progress in the useful arts.

Quantity of experimentation necessary

A person of ordinary skill in the art would have to conduct virtually no experimentation to practice the invention broadly. A large number of inhibitors of telomerase are identified in the specification, along with suitable vehicles and protocols. A person skilled in the art, looking to find additional inhibitors, simply could do what applicants did -- search the literature to find more known inhibitors of telomerase.

The lack of experimentation necessary to practice the invention further brings out why applicants are entitled to broad protection. The Court in Ansul described how easy it is under these circumstances for others to appropriate an inventor's contribution (169 U.S.P.Q. at 762, quoting district court):

With astonishing rapidity [the infringers] used the new discovery and teachings in routine experiments, featuring routine screening techniques, to develop practical uses for the product. None of this would have occurred, of course, if it had not been for Uniroyal's disclosure of the basic secret with sufficient information for researchers to use the compound in their regular sampling procedures.

The presence or absence of working examples

Applicants provided working examples, involving six different inhibitors of telomerase (see Tables I-VI), that demonstrate that compositions including an inhibitor of telomerase work to reduce hair growth.

Courts in analogous situations have found the quantity of testing to be adequate. For example, in In re Boller, 141 U.S.P.Q. 740 (C.C.P.A. 1964), the claimed invention was using volatile neutralizing agents in a chemical process. The patent specification described only a limited number of neutralizing agents that could be used in the process. The court, focusing on the claimed invention rather than on the absence of examples of other neutralizing agents that could be used in the process, held that the claim was broadly enabled:

This is a broad invention and, as noted by the board, appellant is entitled to claims commensurate with the disclosure. Accordingly, we believe that appellant's disclosure, even though of a limited class of "volatile neutralizing agents," is

sufficient to justify claims which define broadly a volatile neutralizing agent. Use of this term is commensurate with the breadth of the invention as disclosed. We think any chemist skilled in this art is fully apprised by appellant's disclosure of what the invention is and is taught how to use it. Appellant need not disclose every operative "volatile neutralizing agent."

Id. at 743 (citation omitted).

The state of the prior art

The prior art cited does not teach any connection between telomerase and hair growth. The invention thus is entitled to broad protection. As the court commented in In re Hogan, 194 U.S.P.Q. 527, 537 (C.C.P.A. 1977) (emphasis added):

[W]e note appellants' argument that their invention is of "pioneer" status. The record reflects no citation of prior art disclosing a solid polymer of 4-methyl-1-pentene, which may suggest that appellants at least broke new ground in a broad sense. On remand, appellants may be found to have been in fact the first to conceive and reduce to practice "a solid polymer" as set forth in claim 13. As pioneers, if such they be, they would deserve broad claims to the broad concept.

The predictability of the art

The chemical/biochemical arts generally are unpredictable. This also applies to the state of the hair growth art when applicants made their invention. Nobody knew that topical application of inhibitors of telomerase actually would work to reduce hair growth until applicants conducted their research. But now that applicants have conducted their work, and established the broad applicability of their invention, it is predictable that telomerase inhibitors applied topically in an appropriate vehicle will work to reduce hair growth.

Breadth of the claims

Claim 1 covers no more than applicants' contribution -- the topical use of inhibitors of telomerase to reduce hair growth.

Specific concerns of the Examiner

The specific concerns of the Examiner, to the extent they are understood, appear to relate to a failure by applicants to recite in claim 1 every compound that is capable of inhibiting telomerase. But as explained above, claim 1 does not cover "inhibitors of telomerase" per se. Rather, claim 1 covers the use of inhibitors of telomerase to treat a specific condition. All that is required under 35 U.S.C. § 112, ¶ 1 is for applicants to name a representative number of

compounds that inhibit telomerase. As discussed above, applicants named a large number of known compounds that have this activity.

The Examiner cites two court decisions, General Electric Co. v. Wabash Appliance, 37 U.S.P.Q. 466 (U.S. 1938) and University of California v. Eli Lilly, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997), for support that claim 1 does not meet the enablement requirements of 35 U.S.C. § 112, ¶ 1. Neither decision supports the Examiner's position.

The General Electric case is a 1938 Supreme Court decision that deals with the use of "functional language at the exact point of novelty." However, "the novelty" of claim 1 is not inhibitors of telomerase (such inhibitors are well known) but rather the use of a known class of compounds (inhibitors of telomerase) to treat a specific condition (unwanted hair growth). Under the current legal standards, claim 1 clearly satisfies the enablement requirements of 35 U.S.C. § 112, ¶ 1.

The specific language from Eli Lilly (at 1406) cited by the Examiner was quoted from a section of the decision that does not even deal with the enablement requirements of 35 U.S.C. § 112, ¶ 1. Rather, the cited section of the decision was addressing a rejection of a claim directed to "human insulin cDNA" for failure to satisfy the written description requirement of 35 U.S.C. § 112, ¶ 1. A subsequent portion of the decision discusses the enablement requirements of 35 U.S.C. § 112, ¶ 1 and supports the patentability of claim 1 (43 U.S.P.Q.2d at 1406):

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. This is analogous to enablement of a genus under § 112, ¶ 1, by showing the enablement of a representative number of species within the genus. *See Angstadt*, 537 F.2d at 502-03, 190 USPQ at 218 (deciding that applicants "are *not* required to disclose *every* species encompassed by their claims even in an unpredictable art" and that the disclosure of forty working examples sufficiently described subject matter of claims directed to a generic process); *In re Robins*, 429 F.2d 452, 456-57, 166 USPQ 552, 555 (CCPA 1970) ("Mention of representative compounds encompassed by generic claim language clearly is not required by § 112 or any other provision of the statute. But, where no explicit description of a generic invention is to be found in the specification ... mention of representative compounds may provide an implicit description upon which to base generic claim language." *Cf.*

Gostelli, 872 F.2d at 1012, 10 USPQ2d at 1618 (determining that the disclosure of two chemical compounds within a subgenus did not describe that subgenus); *In re Grimme*, 274 F.2d 949, 952, 124 USPQ 499, 501 (CCPA 1960) (“[I]t has been consistently held that the naming of one member of such a group is not, in itself, a proper basis for a claim to the entire group. However, it may not be necessary to enumerate a plurality of species if a genus is sufficiently identified in an application by ‘other appropriate language.’”) (citations omitted).

35 U.S.C. § 112, ¶ 2 Rejection

Applicants again will focus on claim 1.

According to 35 U.S.C. § 112, ¶ 2:

[t]he specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which applicant regards as his invention.

As the Court explained in *In re Wakefield*, 164 U.S.P.Q. 636, 641 (C.C.P.A. 1970):

The meaning of this provision is simply that an applicant is required to set definite boundaries on the patent protection sought.

The purpose of the requirements of 35 U.S.C. § 112, ¶ 2 is

to provide those who would endeavor, in future enterprise, to approach the area circumscribed by the claims of a patent, with the adequate notice demanded by due process of law, so that they may more readily and accurately determine the boundaries of protection involved and evaluate the possibility of infringement and dominance.

In re Hammack, 166 U.S.P.Q. 204, 208 (C.C.P.A. 1970).

Claim 1 plainly satisfies these standards. The claim has already been discussed thoroughly and relates to a method of reducing hair growth by topical application of a compound of a known class of compounds, inhibitors of telomerase. The meaning of all of the language used in claim 1 is clear. The Examiner again appears to base the rejection on the failure to list in claim 1 every inhibitor of telomerase. This is nothing but a rehash of the lack of enablement position, which applicants dealt with above.

The Examiner cites a Board of Appeals position, *Ex parte Pulvari*, 157 U.S.P.Q. 169 (1966), for the proposition that “[a] claim to a material defined solely in terms of what it can do, or a property thereof, does not particularly point out the claimed invention.” (see paragraph bridging claims 4-5 of the office action). But *Pulvari* concerned a 35 U.S.C. § 112, ¶ 2 rejection